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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,584	03/18/1999	EDUARDO BLUMWALD	4001	4345

7590 05/27/2004

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425 Market Street  
San Francisco, CA 94105-2482

EXAMINER
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KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/271,584	Applicant(s) BLUMWALD ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,8,10-12,14,18,19,21-32,53,54 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56 is/are allowed.
- 6) ☒ Claim(s) 1,5,7,8,10-12,14,18,19,21-32,53 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 March 2004 has been entered.
2. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32, 53-54 and 56 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 1, 5, 8, 10, 12, 14, 18-19, 21-24, 26-28, 30-32 and 53-54 under 35 U.S.C. 102(b) as being clearly anticipated by Young et al (WO 91/06651) is withdrawn in light of Applicant's amendment of the claims to recite hybridization conditions.
5. The rejection of claims 1, 5, 8, 10, 12, 14, 18-19, 21-28, 30-32 and 53-54 under 35 U.S.C. 103(a) as being unpatentable over Young et al (WO 91/06651) in view of Gordon-Kamm et al (1990, Plant Cell 2:603-618) is withdrawn in light of Applicant's amendment of the claims to recite hybridization conditions.

### ***Specification***

6. The amendment filed 10 March 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not

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supported by the original disclosure is as follows: the insertion of hybridization and wash conditions on pg 29, line 17.

The amendments to the specification constitute new matter.

The objection is repeated for the reasons of record as set forth previously. Applicant's arguments and the Declaration of Maris Apse, both filed 10 March 2004 have been fully considered but they are not persuasive.

Applicant urges that US Patent 5,750,848 was incorporated by reference for methods of preparing nucleic acid molecules and vectors and for guidance with respect to experimental assays and probes; Applicant urges that one of skill in the art would recognize that this includes hybridization assays (response pg 12). Dr. Apse states that she would understand hybridization to be a technique used in preparing recombinant nucleic acids molecules and vectors, for example in screening a cDNA library (Declaration ¶4).

This is not found persuasive because preparing nucleic acid molecules and vectors means production of DNA in bacteria like E. coli and its purification. Hybridization is a technique used in cloning, which is not listed among the methods incorporated by reference.

Dr. Apse and Applicant urge that probes include hybridization probes for use in hybridization assays (Declaration ¶5 and response pg 12-13).

This is not found persuasive because the instant probe would be the instant SEQ ID NO:1. Unless the recited patents teach SEQ ID NO:1 ( and a search of the Office's databases of sequences in issued patents did not find prior art on SEQ ID NO:1), they would not provide guidance or support for use of SEQ ID NO:1 as a hybridization probe.

Dr. Apse states that '848 discloses hybridization using a cloned nucleic acid as a hybridization probe to isolate functionally equivalent forms of a cloned nucleic acid and discloses a range of hybridization conditions as exemplary conditions, including those added to the specification (Declaration ¶6).

This is not found persuasive because the recited portion of '848 is directed to isolation of biological equivalents of the *Pseudomonas putida* PhaG by hybridization with that gene; it is not directed to finding functionally equivalent forms of the instant SEQ ID NO:1. Thus, addition of the range of hybridization conditions as exemplary conditions for isolation of functionally equivalent forms of the instant SEQ ID NO:1 is new matter.

Applicant urges that the amendment imports hybridization and wash conditions from column 21, lines 26-36 of '848, and even though '848 does not refer to the conditions as high stringency, they fall within the range defined by Applicant's specification (response pg 13).

This is not found persuasive because the high stringency conditions defined in the specification do not include hybridization and wash times; additionally, the high stringency hybridization conditions defined in the originally filed specification are more stringent than the amended conditions with respect to SSC concentration. Thus, they do not fall within the range defined by Applicant's specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

7. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A protein with Na<sup>+</sup>/H<sup>+</sup> transporter activity would inherently extrude monovalent cations out of the cytosol of the cell in a plant transformed with a nucleic acid encoding it. Thus, claim 12 fails to further limit claim 1.

8. Claims 12, 13, 20-21, 23, 26 and 53 are objected to because of the following informalities:

In claim 12, line 1, a comma should be inserted after "1".

In claim 14, line 1, a comma should be inserted after "12".

In claims 20-21, there should be an article before "progeny".

In claim 21, line 2, "comprise" should be plural.

In claim 23, line 6, there should be a comma after "salicornia".

In claim 26, line 2, there is an improper article before "plant".

In claim 53, line 2, "comprising" should be replaced with --, wherein the method comprises-- and in part (d), there is an improper article before the first "plant".

### ***Claim Rejections - 35 USC § 112***

9. Claims 1, 5, 10-12, 14, 18-19, 21-32 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of a wash time of 15 minutes in part (c) of claims 1 and 18, and part (a, iii) of

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claim 53. Thus, such a recitation constitutes NEW MATTER. In response to this rejection, Applicant is required to cancel the new matter. Applicant's arguments and the Declaration of Dr Apse with respect to the new matter in the specification, and the reasons why this is not persuasive apply to this rejection.

10. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids that encode proteins with 95% identity to SEQ ID NO:2, methods of using the nucleic acids to produce plants, and plants thereby obtained, does not reasonably provide enablement for  $\text{Na}^+/\text{H}^+$  transporter-encoding nucleic acids that hybridize to SEQ ID NO:1, methods of using the nucleic acids to produce plants, and plants thereby obtained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 21 May 2003, and is a retraction of the statement made in the previous advisory action that the claims were enabled. Applicant's arguments filed 10 March 2004 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids that that encode proteins with 95% identity to SEQ ID NO:2 or that hybridize to SEQ ID NO:1, plants transformed with them and methods of using them to produce salt-tolerant plants.

The specification only provides guidance for cloning four Arabidopsis  $\text{Na}^+/\text{H}^+$  antiport cDNAs (pg 55-57) and generation of salt-tolerant Arabidopsis plants by transformation with AtNHX1 (pg 57-59).

The specification also described prophetically the preparation of antibodies (example 1), isolation of homologous nucleic acids from other plants (example 2), expression of the Arabidopsis and homologous genes in plants and yeast (examples 3-6 and 10-11), characterization of exchangers from other plants (examples 7-8), and identification of regulators of antiport activity (example 9).

The instant specification fails to provide guidance for which plants have DNAs that hybridize to SEQ ID NO:1 under the recited conditions.

As the specification does not describe the transformation of any plant with a nucleic acid that hybridizes to SEQ ID NO:1, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with salt-tolerance, if such plants are even obtainable.

Given the claim breadth, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

11. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 21 May 2003, and is a retraction of the statement made in the previous advisory action that the claims were enabled. Applicant's arguments filed 10 March 2004 have been fully considered but they are not persuasive.



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The claims are broadly drawn to a multitude of nucleic acids that encode proteins with 95 % identity to SEQ ID NO:2 or that hybridize to SEQ ID NO:1. However, the specification does not describe nucleic acids that hybridize to SEQ ID NO:1. Thus, Applicant does not describe a representative number of nucleic acids encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Hence, Applicant has not, in fact, described nucleic acids that hybridize to SEQ ID NO:1 within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

12. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32 and 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. These rejections are new; thus, Applicant's arguments filed 10 March 2004 do not apply.

Claims 1 and 18, part (a), and claim 53, part (a) (i), are indefinite in their recitation of "the coding strand shown in SEQ ID NO:1". Both strands of a DNA can code for peptide, even if it may be very short. Thus, it is not clear to which strand the phrase refers.

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Claim 12 lacks antecedent basis for the limitation "said plant transformed with said recombinant nucleic acid molecule" in line 3.

It is unclear in claim 19 if the progeny of the plant cell comprises the expression transgene.

Claim 24 states that the plant comprises a dicot plant. It is unclear what the rest of the plant is. If Applicant means that the plant is a dicot, "comprises" should be replaced with --is--.

Claim 25 is similarly indefinite for stating that the plant comprises a monocot.

Claim 53 is indefinite for its recitation of "in a cell selected from the group consisting of" because the members of the group are not cells.

13. Claim 56 is allowed; the prior art fails to teach or suggest the isolated nucleic acid of SEQ ID NO:1.

### *Conclusion*

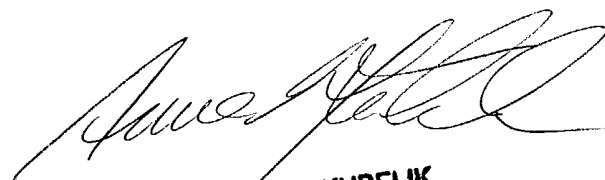
14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (571) 272-0547.

Anne R. Kubelik, Ph.D.  
May 13, 2004



ANNE KUBELIK  
PATENT EXAMINER